

**d.) Remarks.**

Applicant has canceled previously withdrawn claims 6-10, 12-19 and 25-28, amended claims 11 and 30, and added new claims 37-47. Support for the amendments can be found in the existing claims and also in the specification at page 7, lines 17-27. Support for new claims 37-47 can be found in the existing claims and also in the specification, such as at page 7, lines 17-27 and page 12, lines 10-12. No new matter or new issues are raised with these amendments or new claims, and their entry is respectfully requested. Currently claims 11, 29-30 and 33-47 are pending.

**Remarks Regarding 35 U.S.C. § 112, First Paragraph**

Claims 11, 29-30 and 33-36 stand rejected, under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

Although Applicant respectfully disagrees that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed, solely to expedite prosecution, Applicant has amended claims 11 and 30 so that they now both recite an incubation period of less than eight hours. The rejection is therefore now moot, as the Examiner has stated that there is support on page 7 of the specification for an incubation period of less than eight hours. Applicant has also recited incubation times of less than 2 hours and less than 30 minutes in new claims 37 and 42, support for which can also be found on the passage to which the Examiner pointed on page 7 of the specification.

Thus, the rejection of claims 11, 29-30 and 33-36 under 35 U.S.C. § 112, first paragraph, is overcome and Applicant respectfully requests that it be withdrawn.

**Remarks Regarding 35 U.S.C. § 103(a)**

Claims 11, 29 and 33-36 stand rejected under 35 U.S.C. § 103(a), with regard to Shih in view of Litman. Applicant respectfully disagrees.

First, the US Patent number of Litman is stated as being 4,379,925. Applicant assumes that the Examiner meant US Patent Number 4,374,925, which corresponds to the inventor and date of issue indicated in the Office Action.

The Applicant respectfully traverses the Examiner's rejection and asserts that a person skilled in the art having regard to the cited references would not be led directly and without difficulty to the claimed subject matter for the reasons set forth below. Accordingly, the Applicant asserts that such a person would not regard the claimed subject matter as obvious in light of the cited references.

The Applicant asserts that Shih is unrelated to the claimed invention. This reference is directed to the detection of microorganisms in whole blood by colormetric determination (Shih column 1, lines 4-7). A nutrient medium containing a tetrazolium salt is converted to a blue color in response to dehydrogenase formed in the nutrient medium in the presence of microorganisms in the blood (Shih column 1, lines 61-67). However, unlike the claimed invention, Shih does not disclose digestion of the microorganisms or the use of antibodies to detect viability markers accumulated in the microorganisms.

Moreover, the instant application is directed to increasing the speed of detection to less than eight hours. Shih does not disclose or suggest a method capable of decreasing the detection time, or increasing the sensitivity of detection, so drastically as the claimed invention. The Office Action is able to point to merely one cursory mention of speed of detection in Shih, at column 5, line 28, in which only an unspecific assertion of Shih's test being able to be performed "quickly" is present. The Office Action is also not able to point to a single passage which discloses or suggests the claimed 10,000 cfu/mL or less detection anywhere in Shih, because no such suggestion or disclosure exists.

Although increased sensitivity and speed of detection methodologies is a pervasive goal in scientific research, the fact that problems exist and may be allegedly generally known or even identified does not make the resolution of such problems obvious, particularly in fields in which researchers are constantly striving for improved methodologies. The claimed invention provides exponential amplification of sensitivity and speed of detection for microorganisms, which are not suggested or disclosed by the prior art, particularly as the cited references had proved to be incapable of solving these existing problems.

Finally, the Applicant asserts that neither Shih nor Litman, alone or in combination, achieve the same levels of sensitivity (detection of 10,000 cfu/mL or less of microorganisms) as does the claimed invention, and neither Shih nor Litman, alone or in combination, disclose or suggest the methods for achieving sensitivity of the claimed invention. Although the Examiner points to an assertion of an enzyme to which an antibody binds in Litman, the

Office Action's equating Litman's enzymes to Applicant's viability markers on cell fragments of digested microorganisms is erroneous. Specifically, neither Shih nor Litman disclose or suggest employing digestion reagents comprising, for example, lysosome, to *digest* the microorganisms which have been marked with a viability substrate to produce marked cell debris, which is then detected (see specification pages 9-10).

It is at least this extra unique step of digesting microorganisms to produce cell fragments with viability markers adsorbed to the surfaces of cellular debris which contributes to the marked improvement of sensitivity achieved by the claimed invention.

In light of the above, the Applicant asserts that the subject matter of the pending claims is not obvious to a worker skilled in the art having regard to the cited references.

For at least these reasons, as specifically recited in the claims, the claims are not disclosed or suggested in any of the cited references.

Applicant respectfully requests that the rejection of claims 11, 29 and 33-36, under 35 U.S.C. § 103(a), be withdrawn.

#### **Remarks Regarding New Claims 37-47**

Applicant has added new claims 37 – 47. These new claims mirror existing claims 11-36. Claim 37 mirrors claim 11 but recites that the incubation is performed in less than two hours and detection is of 1000 cfu/mL or less of microorganisms. New claim 42 also mirrors existing claim 11, but recites that incubation is less than 30 minutes. The dependent claims from each also mirror the corresponding dependent claims from claim 11.

#### **Conclusion**

In view of the foregoing amendments and/or remarks, reconsideration of the application and issuance of a Notice of Allowance is respectfully requested. If there are any issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the number below.

Should additional fees be necessary in connection with the filing of this Responsive Amendment, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 14-1437, referencing

Appln. No. 10/020,923

Attorney Docket No.: 8109.003.USDV

Attorney Docket No. 8109.003.USDV, for any such fees; and Applicant hereby petitions for any needed extension of time not otherwise accounted for with this submission.

Respectfully submitted,  
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